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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,960	04/25/2001	Dennis K. Watson	10545-014-999	6864

7590 06/24/2004

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/841,960

Applicant(s)

WATSON ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office action is in response to the communication filed 4-25-01.

Claims 1-39 are pending in the instant application.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 22, 23, 25, 27, 28, 30-39, drawn to compositions and treatment methods comprising a modified ets2 protein, classified in classes 514 and 530, subclasses 2 and 350, respectively.
- II. Claims 4-9 drawn to nucleic acids encoding a modified ets2 protein and methods of recombinantly making the protein, classified in classes 435 and 536, subclasses 69.1 and 23.5, respectively.
- III. Claims 10-15, 20, 21, 24-26, 29-33, 36-39, drawn to compositions and treatment methods comprising antisense nucleic acids, classified in classes 514 and 536, subclasses 44 and 24.5, respectively.
- IV. Claims 16-19, drawn to a method of diagnosing cancer, classified in class 435, subclass 6.

Applicants should note that claims 25, 30-33 and 36-39 are generic to the patentably distinct Groups I and III and such claims will be examined according to the limitations of the elected Group.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise compositions that are biologically, chemically, structurally and functionally different and distinct from each other and thus one does not render the other obvious. The protein of Group I is not required to produce the nucleic acid of Group II, and the nucleic acid of Group II is not required to produce the protein of Group I (which can be produced synthetically or purified from cells or tissue). The nucleic acid of Group II is not used in the method of Group I (the administration of a protein). Therefore, the inventions of the two groups are capable of supporting separate patents.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise methods that are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of group I and III comprise steps which are not required for or present in the methods of the other group: treatment methods comprising administration of a modified ets2 protein (Group I); treatment methods comprising the administration of an antisense nucleic acid (Group III). The operation, function and effects of these different methods are distinct from each other. Therefore, the

inventions of these different and distinct groups are capable of supporting separate patents.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise methods that are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Group I and IV comprise steps which are not required for or present in the methods of the other group: treatment methods comprising administration of a modified ets2 protein (Group I); methods of diagnosis comprising measurement of an ets2 gene product (Group IV). The operation, function and effects of these different methods are distinct from each other. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise compositions that are biologically, chemically, structurally and functionally different and distinct from each other and thus one does not render the other obvious. The protein-encoding nucleic acid of Group II is not required to produce the antisense of Group III, and the antisense of Group III is not required to produce the protein-encoding nucleic acid of Group II. The protein-encoding nucleic acid of Group II is not used in the method of Group III (the administration of an

antisense). Therefore, the inventions of the two groups are capable of supporting separate patents.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise compositions that are biologically, chemically, structurally and functionally different and distinct from each other and thus one does not render the other obvious. The nucleic acid encoding a modified ets2 protein of Group II is not used in the diagnostic method of Group IV (method of diagnosis comprising measurement of an ets2 gene product. The operation, function and effects of the nucleic acid encoding a modified ets2 protein are completely different and distinct from the operation, function and effects of the method of Group IV (diagnosis of cancer comprising measuring an ets2 gene product). Therefore, the inventions of the two groups are capable of supporting separate patents.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods comprise steps which are not required for or present in the method of the other group: methods of treatment comprising the administration of antisense (Group III); methods of diagnosis comprising the measurement of an ets2 gene product (Group IV). Thus, the operation, function and effects of the methods of these groups are completely different and distinct. Therefore,

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the inventions of these different and distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Conclusion**

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**  
June 10, 2004

  
**JOHN L. LeGUYADER**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**